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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,094	02/09/2005	Boris P. Kovatchev	3053.128.US	4378
34444 7590 02/25/2008 UNIVERSITY OF VIRGINIA PATENT FOUNDATION 250 WEST MAIN STREET, SUITE 300 CHARLOTTESVILLE, VA 22902				
EXAMINER CLOW, LORI A				
ART UNIT 1631		PAPER NUMBER		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/524,094

**Applicant(s)**

KOVATCHEV ET AL.

**Examiner**

Lori A. Clow, Ph.D.

**Art Unit**

1631

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-226 is/are pending in the application.
- 4a) Of the above claim(s) 40-111 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-39 and 112-226 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 7/19/06
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Election/Restrictions**

Applicant's election with traverse of Group I (claims 1-39 and 112-226) in the reply filed on 28 November 2007 is acknowledged. The traversal is on the ground(s) that Groups I-III all contain the special technical feature of evaluating a patient's management of diabetes by performing predetermined mathematical operations on BG data collected over a certain time period. This is not found persuasive because as recited in the Restriction Requirement of 28 September 2007, the methods of evaluation are specific to each recited Group in which the evaluation of Group I has the feature of calculating blood glucose with specific algorithms that are different from the algorithms for evaluating long term probability in Groups II and III. Therefore, it is maintained that the Groups do NOT share the same technical feature (the same algorithms) and therefore lack unity.

The requirement is still deemed proper and is therefore made FINAL.

Claims 40-111 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 28 November 2007.

Claims 1-39 and 112-226 are herein examined.

### **Priority**

Priority to US Provisional Application 60/402,976, filed 13 August 2002 is acknowledged

### **Information Disclosure Statement**

The Information Disclosure Statement filed 19 July 2006 has been partially considered. References which lack a publication date have not been considered and are indicated by a line through. A signed copy of PTO Form 1449 is included with this Office Action.

### **Drawings**

The drawings submitted 9 February 2005 are accepted.

### **Specification**

The use of the trademark ULTRASMART has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. This is only an example and other trademarks exist in the specification. This requirement applies to all such trademarks present in the instant specification.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### **Claim Objections**

Claim 1 and other claims that contain acronyms that have otherwise NOT previously been spelled out are objected to because of the following informalities: The acronyms in the claims that have not been spelled out must be spelled out the first time that they appear. For instance, in claim 1, HbA<sub>1c</sub> should be stated as glycosylated hemoglobin (HbA<sub>1c</sub>) and BG should

be indicated as blood glucose (BG) . This requirement is for all claims. Appropriate correction is required.

Claims 6, 24, 120, 140, 160, 180, 200, 226 are objected to because of the following informalities: Each of said claims recites, "wherein the preprocessing of the data for each patient using predetermined mathematical formula defined as". The sentence is missing a verb. Perhaps Applicant's intend the claims to read " wherein the preprocessing of the data for each patient using predetermined mathematical formula **is** defined as". Correction is requested.

#### **Claim Rejections - 35 USC § 101**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-39 and 112-226 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1, 135 and 195 are drawn to a method for evaluating the glycosylated hemoglobin (HbA<sub>1c</sub>) of a patient based on blood glucose (BG) comprising preparing data, pre-processing data, estimating the HbA<sub>1c</sub>, and validating data. These methods all include steps that do not include a physical transformation of matter.

As emphasized by the New Interim Guidelines the claims will be evaluated for providing a practical application. A practical application is claimed if the claimed invention physically transforms an article or physical object to a different state or thing, or if the claimed invention otherwise produces a concrete, tangible, and useful result. In the instant case, a physical

transformation of matter is not provided, as the instant claims merely encompass non-physical (i.e. *in-silico*) method steps which do not result in a physical transformation of matter.

Therefore, the claims must be evaluated for providing a practical application that produces a concrete, tangible and useful result. The focus is not on the steps taken to achieve a particular result, but rather the final result achieved by the claimed invention. A claim may be statutory where it recites a result that is concrete (i.e. reproducible), tangible (i.e. communicated to a user), and useful (i.e. a specific and substantial). In the instant case, the claims do not recite a tangible result such that it is useful to one skilled in the art. For these reasons, the instant claims are not statutory.

Claims 19, 38, 155, and 215 are drawn to a system and a computer program product for evaluating the glycosylated hemoglobin (HbA<sub>1c</sub>) of a patient based on blood glucose (BG) comprising preparing data, pre-processing data, estimating the HbA<sub>1c</sub>, and validating data. In the instant claims the “program” or “system”, constitute nonfunctional descriptive material, as no requisite functionality is present to satisfy the practical application requirement. Merely claiming nonfunctional descriptive material, i.e. abstract ideas, stored in a computer-readable medium, in a computer, does not make the claims statutory. Further, data structures, as in a “program” are descriptive material, *per se* and are not statutory because they are not capable of causing a functional change in the computer. See, e.g., Warmerdam, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure *per se* held nonstatutory). Computer programs are viewed as computer listings, *per se*, i.e., the description or expression of the programs, are not physical things. They are neither computer components nor statutory processes, as they are not “acts” being performed. Such claimed computer programs do not define any structural and

functional interrelationships between the computer program and the other claimed elements of a computer that permit that computer program's functionality to be realized.

This rejection could be overcome by amending the claims to recite that a result of the method is "displayed" or "outputted" (e.g. output to a user, a display), or by amending the claims to include a step of a physical transformation of matter (e.g. assay), provided such is supported in the specification as originally filed. For an updated discussion of statutory considerations with regard to non-functional descriptive material and computer-related inventions, see the Guidelines for Patent Eligible Subject Matter in the MPEP 2106, Section IV.

#### **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 119, 130, 199, 219, and 225 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Each of said claims recites, "wherein the preprocessing of the data for each patient comprise: conversion of plasma to whole blood BG mg/dl". It is unclear how a preprocessing technique that takes place in a computer environment, per se, on data, can convert plasma to whole blood". Perhaps Applicant intends that claim read "conversion of plasma data to whole blood BG mg/dl or some other indication that the plasma reading is data to be converted. Clarification is requested.

**Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 19, 37, 38, 135, 155, 195, and 215 are rejected under 35 U.S.C. 102(b) as being anticipated by Cox et al. (Journal of Endocrin. and Metab. (1994) Vol. 79, No. 6, pages 1659-1562; PTO 1449 reference).

The instant claims are drawn to a method, system and computer program for evaluating the HbA<sub>1c</sub> of a patient based on blood glucose (BG) collected over a duration of time comprising preparing data using mathematical formula; preprocessing data, estimating HbA<sub>1c</sub> using a formula, and validating the estimate.

Cox et al. teach a method and system to monitor BG over periods of time intervals, wherein HbA<sub>1c</sub> levels are determined (page 1659, column 2, subjects and methods). Mathematical formulae were used to determine the data parameters (page 1660, column 1).

Claims 1, 5, 19, 23, 37, 38, 135, 139, 155, 159, 195, 199, 215, and 219 are rejected under 35 U.S.C. 102(b) as being anticipated by Kovatchev et al. (Journal of Theor. Med. (2000), pages 1-10; PTO 1449 reference).

The instant claims are drawn to a method, system and computer program for evaluating the HbA<sub>1c</sub> of a patient based on blood glucose (BG) collected over a duration of time comprising



preparing data using mathematical formula; preprocessing data, estimating HbA<sub>1c</sub> using a formula, and validating the estimate.

Kovatchev et al. teach a computational system and method of monitoring BG levels and assessing HbA<sub>1c</sub> (see abstract; see “procedure” section).

In regard to claims 5, 23, 139, 159, 199, and 219, Kovatchev teaches the measurement of low blood glucose and high blood glucose indices (page 5) and the conversion of blood measurements (mg/dl and mmol/l (page 3).

No claims are allowed.

### **Inquiries**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are

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available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

/Lori A. Clow, Ph.D./  
Primary Examiner, Art Unit 1631  
February 27, 2008

**Application Number****Application/Control No.**

10/524,094

**Applicant(s)/Patent under  
Reexamination**

KOVATCHEV ET AL.

**Examiner**

Lori A. Clow, Ph.D.

**Art Unit**

1631